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H. R. 8423

[Report No. 95-714]

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 13, 1977

Read twice and referred to the Committee on Finance

MARCH 22 (legislative day, FEBRUARY 6), 1978

Reported by Mr. LONG, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

AN ACT

To amend titles II and XVIII of the Social Security Act to make improvements in the end stage renal disease program presently authorized under section 226 of that Act, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 ~~That (a) title II of the Social Security Act is amended by~~
4 ~~inserting immediately after section 226 the following new~~
5 ~~section:~~
6 ~~"SPECIAL PROVISIONS RELATING TO COVERAGE UNDER~~
7 ~~MEDICARE PROGRAM FOR END STAGE RENAL DISEASE~~
8 ~~"SEC. 226A. (a) Notwithstanding any provision to~~

1 ~~the contrary in section 226 or title XVIII, every individual~~
 2 ~~who—~~

3 ~~“(1) (A) is fully or currently insured (as such~~
 4 ~~terms are defined in section 214 of this Act) or would~~
 5 ~~be fully or currently insured if his service as an em-~~
 6 ~~ployee (as defined in the Railroad Retirement Act of~~
 7 ~~1974) after December 31, 1936, were included in the~~
 8 ~~term ‘employment’ as defined in this Act, or (B) is~~
 9 ~~entitled to monthly insurance benefits under title II~~
 10 ~~of this Act or an annuity under the Railroad Retire-~~
 11 ~~ment Act of 1974, or (C) is the spouse or dependent~~
 12 ~~child (as defined in regulations) of an individual who~~
 13 ~~is fully or currently insured or would be fully or cur-~~
 14 ~~rently insured if his service as an employee (as defined~~
 15 ~~in the Railroad Retirement Act of 1974) after Decem-~~
 16 ~~ber 31, 1936, were included in the term ‘employment’~~
 17 ~~as defined in this Act, or (D) is the spouse or depend-~~
 18 ~~ent child (as defined in regulations) of an individual~~
 19 ~~entitled to monthly insurance benefits under title II~~
 20 ~~of this Act or an annuity under the Railroad Retire-~~
 21 ~~ment Act of 1974; and~~

22 ~~“(2) is medically determined to have end stage~~
 23 ~~renal disease, and requires renal dialysis or renal trans-~~
 24 ~~plantation for such disease,~~
 25 ~~shall be deemed to be disabled (and to have satisfied the~~

1 ~~requirements of section 226(b)(2)) for purposes of en-~~
2 ~~titlement to benefits under parts A and B of title XVIII,~~
3 ~~subject to the deductible, premium, and coinsurance provi-~~
4 ~~sions of that title.~~

5 ~~“(b) Subject to subsection (e), entitlement of an in-~~
6 ~~dividual to benefits under parts A and B of title XVIII by~~
7 ~~reasons of this section on the basis of end stage renal~~
8 ~~disease—~~

9 ~~“(1) shall begin with—~~

10 ~~“(A) the third month after the month in which~~
11 ~~a regular course of renal dialysis is initiated, or~~

12 ~~“(B) the first month in which such individual~~
13 ~~is admitted as an inpatient to an institution which is~~
14 ~~a hospital meeting the requirements of section 1861~~

15 ~~(e) (and such additional requirements as the Seere-~~
16 ~~tary may prescribe under section 1881(b) for such~~
17 ~~institutions) in preparation for or anticipation of~~
18 ~~kidney transplant surgery, but only if such surgery~~
19 ~~occurs in that month or in either of the next two~~
20 ~~months,~~

21 ~~whichever first occurs; and~~

22 ~~“(2) shall end, in the case of an individual who~~
23 ~~receives a kidney transplant, with the thirty-sixth month~~
24 ~~after the month in which such individual receives such~~
25 ~~transplant or, in the case of an individual who has not~~

1 ~~received a kidney transplant and no longer requires~~
2 ~~a regular course of dialysis, with the twelfth month~~
3 ~~after the month in which such course of dialysis is~~
4 ~~terminated.~~

5 ~~“(e) Notwithstanding the provisions of subsection~~
6 ~~(b)—~~

7 ~~“(1) in the case of any individual who participates~~
8 ~~in a self care dialysis training program prior to the third~~
9 ~~month after the month in which such individual initiates~~
10 ~~a regular course of renal dialysis in a renal disease facil-~~
11 ~~ity or provider of services meeting the requirements of~~
12 ~~section 1881 (b), entitlement to benefits shall begin with~~
13 ~~the month in which such regular course of renal dialysis~~
14 ~~is initiated; and~~

15 ~~“(2) in any case where a kidney transplant fails~~
16 ~~(whether during or after the thirty six month period~~
17 ~~specified in subsection (b) (2)) and as a result the~~
18 ~~individual who received such transplant initiates or~~
19 ~~resumes a regular course of renal dialysis, such individ-~~
20 ~~ual shall be entitled to benefits under parts A and B of~~
21 ~~title XVIII beginning with the month in which such~~
22 ~~failure occurs.”.~~

23 ~~(b) Section 226 of such Act is amended—~~

24 ~~(1) by striking out subsections (e), (f), and (g),~~
25 ~~and~~

1 ~~(2) by redesignating subsections (h) and (i) as~~
2 ~~subsections (e) and (f), respectively.~~

3 ~~SEC. 2. Part C of title XVIII of the Social Security Act~~
4 ~~is amended by adding at the end thereof the following new~~
5 ~~section:-~~

6 ~~"MEDICARE COVERAGE FOR END STAGE RENAL DISEASE~~
7 ~~PATIENTS~~

8 ~~"SEC. 1881. (a) The benefits provided by parts A and~~
9 ~~B of this title shall include benefits for individuals who have~~
10 ~~been determined to have end stage renal disease as provided~~
11 ~~in section 226A, and benefits for kidney donors as provided~~
12 ~~in subsection (d) of this section. Notwithstanding any~~
13 ~~other provision of this title, the type, duration, and scope of~~
14 ~~the benefit provided by parts A and B with respect to indi-~~
15 ~~viduals who have been determined to have end stage renal~~
16 ~~disease and who are entitled to such benefits without regard~~
17 ~~to section 226A shall in no case be less than the type, dura-~~
18 ~~tion, and scope of the benefits so provided for individuals~~
19 ~~entitled to such benefits solely by reason of that section.~~

20 ~~"(b) (1) Payments under this title with respect to serv-~~
21 ~~ices, in addition to services for which payment would other-~~
22 ~~wise be made under this title, furnished to individuals who~~
23 ~~have been determined to have end stage renal disease shall~~
24 ~~include (A) payments on behalf of such individuals to pro-~~
25 ~~viders of services and renal dialysis facilities which meet such~~

1 ~~requirements as the Secretary shall by regulation prescribe~~
2 ~~for institutional dialysis services, transplantation services,~~
3 ~~self dialysis services in a self care dialysis unit maintained by~~
4 ~~the provider or facility, and home dialysis support serv-~~
5 ~~ices which are furnished by the provider or facility, and~~
6 ~~(B) payments to or on behalf of such individuals for home~~
7 ~~dialysis supplies and equipment. The requirements prescribed~~
8 ~~by the Secretary under subparagraph (A) shall include~~
9 ~~requirements for a minimum utilization rate for covered pro-~~
10 ~~cedures and for self dialysis training programs.~~

11 ~~“(2) (A) With respect to payments for dialysis serv-~~
12 ~~ices furnished by providers of services and renal dialysis fa-~~
13 ~~cilities to individuals determined to have end stage renal dis-~~
14 ~~ease for which payments may be made under part B of this~~
15 ~~title, such payments (unless otherwise provided in this sec-~~
16 ~~tion) shall be equal to 80 percent of the amounts determined~~
17 ~~in accordance with subparagraph (B); and with respect to~~
18 ~~payments for services for which payments may be made~~
19 ~~under part A of this title, the amounts of such payments~~
20 ~~(which amounts shall not exceed, in respect to costs in pro-~~
21 ~~curing organs attributable to payments made to an organ~~
22 ~~procurement agency or histocompatibility laboratory, the~~
23 ~~costs incurred by that agency or laboratory) shall be deter-~~
24 ~~mined in accordance with section 1861 (v). Payments shall~~
25 ~~be made to a renal dialysis facility only if it agrees to accept~~

1 ~~such payments as payment in full for covered services, ex-~~
 2 ~~cept for payment by the individual of 20 percent of the costs~~
 3 ~~for such services (as determined in accordance with sub-~~
 4 ~~paragraph (B)) and the deductible amount imposed by sec-~~
 5 ~~tion 1833 (b).~~

6 ~~“(B) The Secretary shall prescribe in regulations any~~
 7 ~~methods and procedures to (i) determine the costs incurred~~
 8 ~~by providers of services and renal dialysis facilities in fur-~~
 9 ~~nishing covered services to individuals determined to have~~
 10 ~~end-stage renal disease, and (ii) determine, on a cost-related~~
 11 ~~basis or other economical and equitable basis (including any~~
 12 ~~basis authorized under section 1861 (v)), the amounts of~~
 13 ~~payments to be made for part B services furnished by such~~
 14 ~~providers and facilities to such individuals. Such regulations~~
 15 ~~shall provide for the implementation of appropriate incen-~~
 16 ~~tives for encouraging more efficient and effective delivery of~~
 17 ~~services (consistent with quality care), and shall include,~~
 18 ~~to the extent determined feasible by the Secretary, prospec-~~
 19 ~~tively set rates, a system for classifying comparable providers~~
 20 ~~and facilities, and target rates with arrangements for shar-~~
 21 ~~ing such reductions in costs as may be attributable to more~~
 22 ~~efficient and effective delivery of services.~~

23 ~~“(C) Such regulations, in the case of services furnished~~
 24 ~~by proprietary providers and facilities may include, if the~~
 25 ~~Secretary finds it feasible and appropriate, provision for~~

1 ~~recognition of a reasonable rate of return on equity capital,~~
2 ~~providing such rate of return does not exceed the rate of~~
3 ~~return stipulated in section 1861 (v) (1) (B).~~

4 ~~“(D) For purposes of section 1878, a renal dialysis~~
5 ~~facility shall be treated as a provider of services.~~

6 ~~“(3) With respect to payments for services furnished~~
7 ~~by physicians to individuals determined to have end stage~~
8 ~~renal disease, the Secretary may make payment for such~~
9 ~~services on an individual service basis (and may, in such~~
10 ~~case, make payment on the basis of the customary and pre-~~
11 ~~vailing charges of other physicians for comparable services),~~
12 ~~or on the basis of an aggregate of services provided over a~~
13 ~~period of time (as defined in regulations); and, with respect~~
14 ~~to aggregate physician services expected to be provided over~~
15 ~~a period of time, the Secretary may provide for payment on~~
16 ~~a comprehensive fee basis.~~

17 ~~“(4) Pursuant to agreements with approved providers~~
18 ~~of services and renal dialysis facilities, the Secretary may~~
19 ~~make payment to such providers and facilities for the cost of~~
20 ~~home dialysis supplies and equipment and home dialysis~~
21 ~~support services furnished to patients dialyzing at home~~
22 ~~whose home dialysis care is under the direct supervision of~~
23 ~~such provider or facility, on the basis of a target reimburse-~~
24 ~~ment rate (as defined in paragraph (6)).~~

1 ~~“(5) An agreement under paragraph (4) shall re-~~
2 ~~quire that the provider or facility will—~~

3 ~~“(A) assume full responsibility for directly ob-~~
4 ~~taining or arranging for the provision of—~~

5 ~~“(i) such medically necessary dialysis equip-~~
6 ~~ment as is prescribed by the attending physician;~~

7 ~~“(ii) dialysis equipment maintenance and re-~~
8 ~~pair services;~~

9 ~~“(iii) the purchase and delivery of all neces-~~
10 ~~sary medical supplies; and~~

11 ~~“(iv) where necessary, the services of trained~~
12 ~~home dialysis aides;~~

13 ~~“(B) perform all such administrative functions and~~
14 ~~maintain such information and records as the Secretary~~
15 ~~may require to verify the transactions and arrangements~~
16 ~~described in subparagraph (A);~~

17 ~~“(C) submit such cost reports, data, and informa-~~
18 ~~tion as the Secretary may require with respect to the~~
19 ~~costs incurred for equipment, supplies, and services~~
20 ~~furnished to the facility's home dialysis patient popu-~~
21 ~~lation; and~~

22 ~~“(D) provide for full access for the Secretary to~~
23 ~~all such records, data, and information as he may require~~
24 ~~to perform his functions under this section.~~

~~1 “(6) The Secretary shall establish, for each calendar~~
~~2 year, commencing with January 1, 1978, a target reimburse-~~
~~3 ment rate for home dialysis which shall be adjusted for~~
~~4 regional variations in the cost of providing home dialysis.~~
~~5 In establishing such a rate, the Secretary shall include—~~
~~6 “(A) the Secretary’s estimate of the cost of pro-~~
~~7 viding medically necessary home dialysis supplies and~~
~~8 equipment;~~
~~9 “(B) an allowance, in an amount determined by the~~
~~10 Secretary, to cover the cost of providing personnel to~~
~~11 aid in home dialysis; and~~
~~12 “(C) an allowance, in an amount determined by~~
~~13 the Secretary, to cover administrative costs and to pro-~~
~~14 vide an incentive for the efficient delivery of home~~
~~15 dialysis;~~
~~16 but in no event shall such target rate exceed 70 percent of~~
~~17 the national average payment, adjusted for regional varia-~~
~~18 tions, for a maintenance dialysis service furnished in ap-~~
~~19 proved providers and facilities during the preceding fiscal~~
~~20 year. Any such target rate so established shall be utilized,~~
~~21 without renegotiation of the rate, throughout the calendar~~
~~22 year for which it is established. During the last quarter of~~
~~23 each calendar year, the Secretary shall establish a home~~
~~24 dialysis target reimbursement rate for the next calendar year~~
~~25 based on the most recent data available to the Secretary~~

1 ~~at the time. In establishing any rate under this paragraph,~~
2 ~~the Secretary may utilize a competitive bid procedure, a pro-~~
3 ~~negotiated rate procedure, or any other procedure which the~~
4 ~~Secretary determines is appropriate and feasible in order to~~
5 ~~carry out this paragraph in an effective and efficient~~
6 ~~manner.~~

7 ~~“(7) For purposes of this title, the term ‘home dialysis~~
8 ~~supplies and equipment’ means medically necessary supplies~~
9 ~~and equipment (including supportive equipment) required~~
10 ~~by an individual suffering from end-stage renal disease in~~
11 ~~connection with renal dialysis carried out in his home (as~~
12 ~~defined in regulations), including obtaining, installing, and~~
13 ~~maintaining such equipment.~~

14 ~~“(8) For purposes of this title, the term ‘self-care home~~
15 ~~dialysis support services’, to the extent permitted in regula-~~
16 ~~tion, means—~~

17 ~~“(A) periodic monitoring of the patient’s home~~
18 ~~adaptation, including visits by qualified provider or~~
19 ~~facility personnel (as defined in regulations), so long as~~
20 ~~this is done in accordance with a plan prepared and~~
21 ~~periodically reviewed by a professional team (as defined~~
22 ~~in regulations) including the individual’s physician;~~

23 ~~“(B) installation and maintenance of dialysis~~
24 ~~equipment;~~

1 ~~“(C) testing and appropriate treatment of the~~
2 ~~water; and~~

3 ~~“(D) such additional supportive services as the~~
4 ~~Secretary finds appropriate and desirable.~~

5 ~~“(9) For purposes of this title, the term ‘self-care di-~~
6 ~~alysis unit’ means a renal disease facility or a distinct part~~
7 ~~of such facility or of a provider of services, which has been~~
8 ~~approved by the Secretary to make self dialysis services, as~~
9 ~~defined by the Secretary in regulations, available to indi-~~
10 ~~viduals who have been trained for self dialysis. A self-care~~
11 ~~dialysis unit must, at a minimum, furnish the services, equip-~~
12 ~~ment and supplies needed for self-care dialysis, have patient-~~
13 ~~staff ratios which are appropriate to self dialysis (allowing~~
14 ~~for such appropriate lesser degree of ongoing medical super-~~
15 ~~vision and assistance of ancillary personnel than is required~~
16 ~~for full care maintenance dialysis), and meet such other re-~~
17 ~~quirements as the Secretary may prescribe with respect to~~
18 ~~the quality and cost-effectiveness of services.~~

19 ~~“(e) (1) For the purpose of assuring effective and effi-~~
20 ~~cient administration of the benefits provided under this~~
21 ~~section, the Secretary shall establish, in accordance with~~
22 ~~such criteria as he finds appropriate, renal disease net-~~
23 ~~work areas, such network organizations (including a medi-~~
24 ~~cal review board for each network area) as he finds neces-~~
25 ~~sary to accomplish such purpose, and a national end stage~~

1 renal disease medical information system. The Secretary
 2 may by regulations provide for such coordination of net-
 3 work planning and quality assurance activities and such
 4 exchange of data and information among agencies with re-
 5 sponsibilities for health planning and quality assurance ac-
 6 tivities under Federal law as is consistent with the eco-
 7 nomical and efficient administration of this section and with
 8 the responsibilities established for network organizations and
 9 medical review boards under this section.

10 ~~“(2) The network organization and the medical review~~
 11 ~~board of each network shall be responsible, in addition to~~
 12 ~~such other duties and functions as may be prescribed by the~~
 13 ~~Secretary, for—~~

14 ~~“(A) encouraging, to the maximum extent possi-~~
 15 ~~ble, consistent with sound medical practice, the use of~~
 16 ~~those treatment settings most compatible with the suc-~~
 17 ~~cessful rehabilitation of the patient;~~

18 ~~“(B) developing, on the basis of normative data~~
 19 ~~derived from the renal disease medical information~~
 20 ~~system and criteria and standards developed within the~~
 21 ~~network, network goals relating to the quality and~~
 22 ~~appropriateness of patient care, including goals with~~
 23 ~~respect to the appropriate proportion of network patients~~
 24 ~~dialyzing in self-care settings and undergoing or prepar-~~
 25 ~~ing for transplantation;~~

1 ~~“(C) evaluating the procedures by which facilities~~
2 ~~and providers in the network assess the appropriateness~~
3 ~~of patients for proposed treatment modalities;~~

4 ~~“(D) identifying facilities and providers that are~~
5 ~~not cooperating toward meeting network goals; request-~~
6 ~~ing explanations and plans for correction from such~~
7 ~~facilities and providers; and approving or recommending~~
8 ~~plans for such correction; and-~~

9 ~~“(E) submitting an annual report to the Secretary~~
10 ~~on July 1 of each year which shall include a full state-~~
11 ~~ment of the network's goals, data on the network's~~
12 ~~performance in meeting its goals (including data on the~~
13 ~~comparative performance of facilities and providers with~~
14 ~~respect to the identification and placement of suitable~~
15 ~~candidates in self-care settings and transplantation);~~
16 ~~identification of those facilities that have consistently~~
17 ~~failed to cooperate with network goals, and recommen-~~
18 ~~dations with respect to the need for additional or alter-~~
19 ~~native services or facilities in the network in order to~~
20 ~~meet the network goals, including self-dialysis training,~~
21 ~~transplantation, and organ procurement facilities.~~

22 ~~“(3) The Secretary shall evaluate the adequacy of each~~
23 ~~network's goals, in relation to the national objective estab-~~
24 ~~lished in accordance with paragraph (4), and the perform-~~
25 ~~ance of the network in meeting these goals, and may rec-~~

1 ~~commend such modifications in the goals and the methods~~
2 ~~for achieving them as he deems appropriate. Where the Sec-~~
3 ~~retary determines, on the basis of the data contained in the~~
4 ~~network's annual report and such other relevant data as may~~
5 ~~be available to him, that a facility or provider has consistently~~
6 ~~failed to cooperate with network plans and goals, he may~~
7 ~~terminate or withhold certification of such facility or provider~~
8 ~~(for purposes of payment for services furnished to individuals~~
9 ~~with end stage renal disease) until he determines that such~~
10 ~~provider or facility is making reasonable and appropriate~~
11 ~~efforts to cooperate with the network's plans and goals.~~

12 ~~“(4) The national objective with respect to the appro-~~
13 ~~priate proportion of patients in self-dialysis settings and pre-~~
14 ~~paring for or undertaking transplantation is that a majority~~
15 ~~of new patients being accepted for end stage renal disease~~
16 ~~treatment should be in self-dialysis settings or be transplanted.~~
17 ~~The Secretary shall, after consultation with appropriate pro-~~
18 ~~fessional and network organizations, and after taking into~~
19 ~~account available evidence relating to developments in re-~~
20 ~~search, treatment methods and technology, periodically eval-~~
21 ~~uate and, when he determines necessary, recommend revision~~
22 ~~of the national objective to the Congress.~~

23 ~~“(5) The Secretary shall, in determining whether to~~
24 ~~certify additional facilities or expansion of existing facilities~~
25 ~~within a network, take into account the network's goals and~~

1 ~~performance as reflected in the network's annual report, and~~
2 ~~assure himself that where a network has a low self-dialysis~~
3 ~~treatment percentage such percentage can be satisfactorily~~
4 ~~justified before certifying additional beds or facilities.~~

5 ~~“(6) The Secretary shall, on the basis of the annual~~
6 ~~network reports, determine the extent to which self-dialysis~~
7 ~~training within each network is adequate to the patient~~
8 ~~size and referral patterns of the area. Where the Secretary~~
9 ~~finds that self-training programs in any network are of in-~~
10 ~~sufficient capacity or are not distributed throughout the net-~~
11 ~~work in a manner which assures that self-dialysis training~~
12 ~~is adequate to meet the needs of individuals with renal~~
13 ~~disease, he shall place in effect a program under which self-~~
14 ~~dialysis training is provided in renal disease facilities or pro-~~
15 ~~viders which shall be designated by him for this purpose.~~
16 ~~Where a provider or facility so designated is subsequently~~
17 ~~found by the Secretary to have failed to provide the required~~
18 ~~self-dialysis training, he may terminate or withhold certifica-~~
19 ~~tion of such provider or facility (for purposes of payment for~~
20 ~~services furnished to individuals with end stage renal dis-~~
21 ~~ease) until such provider or facility is in compliance with the~~
22 ~~requirements concerning the provision of self-dialysis~~
23 ~~training.~~

24 ~~“(d) Notwithstanding any provision to the contrary~~
25 ~~in section 226, any individual who donates a kidney for~~

1 ~~transplant surgery shall be entitled to benefits under parts~~
 2 ~~A and B of this title with respect to such donation. Reim-~~
 3 ~~bursment for the reasonable expenses incurred by such an~~
 4 ~~individual with respect to a kidney donation shall be made~~
 5 ~~(without regard to the deductible, premium, and coinsur-~~
 6 ~~ance provisions of this title), in such manner as may be~~
 7 ~~prescribed by the Secretary in regulations, for all prepara-~~
 8 ~~tory, operation, and postoperation recovery costs associated~~
 9 ~~with such donation, including but not limited to the costs~~
 10 ~~for which payment could be made if he were an eligible~~
 11 ~~individual for purposes of parts A and B of this title with-~~
 12 ~~out regard to this subsection. Postoperation recovery costs~~
 13 ~~shall be limited to the actual period of recovery.~~

14 ~~“(c) (1) Notwithstanding any other provision of this~~
 15 ~~title, the Secretary may, pursuant to agreements with~~
 16 ~~approved providers of services and renal dialysis facilities,~~
 17 ~~reimburse such providers and facilities (without regard to~~
 18 ~~the deductible and coinsurance provisions of this title) for~~
 19 ~~the reasonable cost of the purchase, installation, maintenance~~
 20 ~~and reconditioning for subsequent use of artificial kidney~~
 21 ~~and automated dialysis peritoneal machines (including sup-~~
 22 ~~portive equipment) which are to be used exclusively by~~
 23 ~~entitled individuals dialyzing at home.~~

24 ~~“(2) An agreement under this subsection shall require~~
 25 ~~that the provider or facility will—~~

1 ~~“(A) make the equipment available for use only~~
2 ~~by entitled individuals dialyzing at home;~~

3 ~~“(B) recondition the equipment, as needed, for~~
4 ~~reuse by such individuals throughout the useful life of~~
5 ~~the equipment, including modification of the equipment~~
6 ~~consistent with advances in research and technology;~~

7 ~~“(C) provide for full access for the Secretary to~~
8 ~~all records and information relating to the purchase,~~
9 ~~maintenance, and use of the equipment; and~~

10 ~~“(D) submit such reports, data, and information~~
11 ~~as the Secretary may require with respect to the cost,~~
12 ~~management, and use of the equipment.~~

13 ~~“(3) For purposes of this section, the term ‘sup-~~
14 ~~portive equipment’ includes blood pumps, heparin pumps,~~
15 ~~bubble detectors, other alarm systems, and such other items~~
16 ~~as the Secretary may determine are medically necessary.~~

17 ~~“(f) (1) The Secretary shall initiate and carry out, at~~
18 ~~selected locations in the United States, pilot projects under~~
19 ~~which financial assistance in the purchase of new or used~~
20 ~~durable medical equipment for renal dialysis is provided to~~
21 ~~individuals suffering from end stage renal disease at the~~
22 ~~time home dialysis is begun, with provision for a trial~~
23 ~~period to assure successful adaptation to home dialysis~~
24 ~~before the actual purchase of such equipment.~~

25 ~~“(2) The Secretary shall conduct experiments to~~

1 ~~evaluate methods for reducing the costs of the end stage~~
2 ~~renal disease program. Such experiments shall include~~
3 ~~(without being limited to) reimbursement for nurses and~~
4 ~~dialysis technicians to assist with home dialysis, reimburse-~~
5 ~~ment to family members assisting with home dialysis, and~~
6 ~~(to the extent medically sound) incentives to home dial-~~
7 ~~ysis patients to clean and reuse their dialysis filters.~~

8 ~~“(3) The Secretary shall conduct experiments to eval-~~
9 ~~ate methods of dietary control for reducing the costs of the~~
10 ~~end stage renal disease program, including (without being~~
11 ~~limited to) the use of protein controlled products to delay~~
12 ~~the necessity for, or reduce the frequency of, dialysis in the~~
13 ~~treatment of end stage renal disease.~~

14 ~~“(4) The Secretary shall conduct a comprehensive~~
15 ~~study of methods for increasing public participation in kidney~~
16 ~~donation and other organ donation programs.~~

17 ~~“(5) The Secretary shall conduct a full and complete~~
18 ~~study of the reimbursement of physicians for services fur-~~
19 ~~nished to patients with end stage renal disease under this~~
20 ~~title, giving particular attention to the range of payments to~~
21 ~~physicians for such services, the average amounts of such~~
22 ~~payments, and the number of hours devoted to furnishing~~
23 ~~such services to patients at home, in renal disease facilities,~~
24 ~~in hospitals, and elsewhere.~~

25 ~~“(6) The Secretary shall conduct a study of the num-~~

~~ber of patients with end stage renal disease who are not~~
~~eligible for benefits with respect to such disease under this~~
~~title (by reason of this section or otherwise), and of the~~
~~economic impact of such noneligibility of such individuals.~~
~~Such study shall include consideration of mechanisms where-~~
~~by governmental and other health plans might be instituted~~
~~or modified to permit the purchase of actuarially sound~~
~~coverage for the costs of end stage renal disease.~~

~~“(7) The Secretary shall submit to the Congress no~~
~~later than October 1, 1978, a full report on the experiments~~
~~conducted under paragraphs (1), (2), and (3) and the~~
~~studies under paragraphs (4), (5), and (6). Such report~~
~~shall include any recommendations for legislative changes~~
~~which the Secretary finds necessary or desirable as a result~~
~~of such experiments and studies.~~

~~“(g) The Secretary shall submit to the Congress on~~
~~October 1, 1978, and on October 1 of each year thereafter,~~
~~a report on the end stage renal disease program, including~~
~~but not limited to—~~

~~“(1) the number of patients, nationally and by~~
~~renal disease network, on dialysis (self dialysis or other-~~
~~wise) at home and in facilities;~~

~~“(2) the number of new patients entering dialysis~~
~~at home and in facilities during the year;~~

1 ~~“(3) the number of facilities providing dialysis and~~
2 ~~the utilization rates of those facilities;~~

3 ~~“(4) the number of kidney transplants, by source~~
4 ~~of donor organ;~~

5 ~~“(5) the number of patients awaiting organs for~~
6 ~~transplant;~~

7 ~~“(6) the number of transplant failures;~~

8 ~~“(7) the range of costs of kidney acquisitions, by~~
9 ~~type of facility and by region;~~

10 ~~“(8) the number of facilities providing transplants~~
11 ~~and the number of transplants performed per facility;~~

12 ~~“(9) patient mortality and morbidity rates;~~

13 ~~“(10) the average annual cost of hospitalization for~~
14 ~~ancillary problems in dialysis and transplant patients,~~
15 ~~and drug costs for transplant patients;~~

16 ~~“(11) medicare payment rates for dialysis, trans-~~
17 ~~plant procedures, and physician services, along with~~
18 ~~any changes in such rates during the year and the~~
19 ~~reasons for those changes;~~

20 ~~“(12) the results of cost saving experiments;~~

21 ~~“(13) the results of basic kidney disease research~~
22 ~~conducted by the Federal Government, private institu-~~
23 ~~tions, and foreign governments;~~

1 ~~“(14) information on the activities of medical re-~~
 2 ~~view boards and other network organizations; and~~

3 ~~“(15) estimated program costs over the next five~~
 4 ~~years.”~~

5 ~~SEC. 3. (a) Section 226 (a) of the Social Security Act~~
 6 ~~is amended—~~

7 ~~(1) by striking out “specified in subparagraph~~
 8 ~~(B)” and inserting in lieu thereof “specified in para-~~
 9 ~~graph (1)”;~~ and

10 ~~(2) by striking out “specified in subparagraphs~~
 11 ~~(A) and (B)” and inserting in lieu thereof “specified~~
 12 ~~in paragraphs (1) and (2)”.~~

13 ~~(b) Paragraphs (2) and (3) of section 226 (c) of~~
 14 ~~such Act (as redesignated by subsection (b) (2) of the~~
 15 ~~first section of this Act) are each amended by striking out~~
 16 ~~“subsection b” and inserting in lieu thereof “subsection~~
 17 ~~(b)”.~~

18 ~~SEC. 4. (a) Section 1833 (a) (1) of the Social Security~~
 19 ~~Act is amended—~~

20 ~~(1) by striking out “and” at the end of clause (C),~~
 21 ~~and—~~

22 ~~(2) by adding the following after “and” in clause~~
 23 ~~(D):~~

24 ~~“(E) with respect to services furnished to individ-~~
 25 ~~uals who have been determined to have end stage renal~~

1 ~~disease, the amounts paid shall be determined pursuant~~
 2 ~~to section 1881, and”.~~

3 ~~(b) Section 1833 (a) (2) of such Act is amended by~~
 4 ~~inserting “(unless otherwise specified in section 1881)”~~
 5 ~~after “other services”.~~

6 ~~(c) Section 1861 (s) (2) of such Act is amended—~~

7 ~~(1) by striking out “and” at the end of clause (C);~~

8 ~~(2) by inserting “and” at the end of clause (D);~~

9 ~~and~~

10 ~~(3) by adding the following new clause after sub-~~
 11 ~~clause (D):~~

12 ~~“(E) home dialysis supplies and equipment, self-~~
 13 ~~care home dialysis support services, and self-dialysis~~
 14 ~~services;”.~~

15 ~~(d) The first sentence of section 1866 (a) (2) (A) of~~
 16 ~~such Act is amended by inserting the following before the~~
 17 ~~period: “(but in the case of items and services furnished~~
 18 ~~to individuals with end-stage renal disease, an amount equal~~
 19 ~~to 20 percent of the estimated amounts for such items and~~
 20 ~~services calculated on the cost-related basis established by~~
 21 ~~the Secretary)”.~~

22 ~~SEC. 5. The third sentence of section 1817 (b) of the~~
 23 ~~Social Security Act, and the third sentence of section 1841~~
 24 ~~(b) of such Act, are each amended by striking out “Com-~~
 25 ~~missioner of Social Security” and inserting in lieu thereof~~

1 ~~“Administrator of the Health Care Financing Administra-~~
 2 ~~tion.~~

3 ~~SEC. 6. The amendments made by this Act shall be~~
 4 ~~come effective with respect to services, supplies, and equip-~~
 5 ~~ment furnished after the third calendar month which begins~~
 6 ~~after the date of the enactment of this Act, except that those~~
 7 ~~amendments providing for the implementation of an incen-~~
 8 ~~tive reimbursement system shall become effective with re-~~
 9 ~~spect to a facility's or provider's first accounting period which~~
 10 ~~begins on or after October 1, 1978.~~

11 *That (a) title II of the Social Security Act is amended by*
 12 *inserting immediately after section 226 the following new*
 13 *section:*

14 *“SPECIAL PROVISIONS RELATING TO COVERAGE UNDER*
 15 *MEDICARE PROGRAM FOR END STAGE RENAL DISEASE*

16 *“SEC. 226A. (a) Notwithstanding any provision to*
 17 *the contrary in section 226 of title XVIII, every individual*
 18 *who—*

19 *“(1)(A) is fully or currently insured (as such*
 20 *terms are defined in section 214 of this Act) or would*
 21 *be fully or currently insured if his service as an em-*
 22 *ployee (as defined in the Railroad Retirement Act of*
 23 *1974) after December 31, 1936, were included in the*
 24 *term ‘employment’ as defined in this Act, or (B) is*
 25 *entitled to monthly insurance benefits under title II*

1 of this Act or an annuity under the Railroad Retire-
2 ment Act of 1974, or (C) is the spouse or dependent
3 child (as defined in regulations) of an individual who
4 is fully or currently insured or would be fully or cur-
5 rently insured if his service as an employee (as defined
6 in the Railroad Retirement Act of 1974) after Decem-
7 ber 31, 1936, were included in the term 'employment'
8 as defined in this Act, or (D) is the spouse or depend-
9 ent child (as defined in regulations) of an individual
10 entitled to monthly insurance benefits under title II
11 of this Act or an annuity under the Railroad Retire-
12 ment Act of 1974; and

13 “(2) is medically determined to have end stage
14 renal disease; and

15 “(3) has filed an application for benefits under this
16 section,

17 shall, in accordance with the succeeding provisions of this
18 section, be entitled to benefits under part A and eligible to
19 enroll under part B of title XVIII, subject to the deductible,
20 premium, and coinsurance provisions of that title.

21 “(b) Subject to subsection (c), entitlement of an indi-
22 vidual to benefits under part A and eligibility to enroll under
23 part B of title XVIII by reasons of this section on the basis
24 of end stage renal disease—

25 “(1) shall begin with—

1 “(A) the third month after the month in which
2 a regular course of renal dialysis is initiated, or

3 “(B) the month in which such individual
4 receives a kidney transplant, or (if earlier) the first
5 month in which such individual is admitted as an
6 inpatient to an institution which is a hospital meet-
7 ing the requirements of section 1861(c) (and such
8 additional requirements as the Secretary may pre-
9 scribe under section 1881(b) for such institutions)
10 in preparation for or anticipation of kidney trans-
11 plantation, but only if such transplantation occurs
12 in that month or in either of the next two months,
13 whichever first occurs (but no earlier than one year
14 preceding the month of the filing of an application for
15 benefits under this section); and

16 “(2) shall end, in the case of an individual who
17 receives a kidney transplant, with the thirty-sixth month
18 after the month in which such individual receives such
19 transplant or, in the case of an individual who has not
20 received a kidney transplant, and no longer requires a
21 regular course of dialysis, with the twelfth month after
22 the month in which such course of dialysis is terminated.

23 “(c) Notwithstanding the provisions of subsection (b)—

24 “(1) in the case of any individual who participates
25 in a self-dialysis training program prior to the third

month after the month in which such individual initiates a regular course of renal dialysis in a renal dialysis facility or provider of services meeting the requirements of section 1881(b), entitlement to benefits under part A and eligibility to enroll under part B of title XVIII shall begin with the month in which such regular course of renal dialysis is initiated;

“(2) in any case in which a kidney transplant fails (whether during or after the thirty-six-month period specified in subsection (b)(2)) and as a result the individual who received such transplant initiates or resumes a regular course of renal dialysis, entitlement to benefits under part A and eligibility to enroll under part B of title XVIII shall begin with the month in which such course is initiated or resumed; and

“(3) in any case in which a regular course of renal dialysis is resumed subsequent to the termination of an earlier course, entitlement to benefits under part A and eligibility to enroll under part B of title XVIII shall begin with the month in which such regular course of renal dialysis is resumed.”.

(b) Section 226 of such Act is amended—

(1) by striking out subsections (e), (f), and (g),
and

(2) by redesignating subsections (h) and (i) as subsections (e) and (f), respectively.

3 *SEC. 2. Part C of title XVIII of the Social Security*
4 *Act is amended by adding at the end thereof the following*
5 *new section:*

6 “MEDICARE COVERAGE FOR END STAGE RENAL DISEASE
7 PATIENTS

8 “SEC. 1881. (a) The benefits provided by parts A and
9 B of this title shall include benefits for individuals who have
10 been determined to have end-stage renal disease as provided
11 in section 226A, and benefits for kidney donors as provided
12 in subsection (d) of this section. Notwithstanding any
13 other provision of this title, the type, duration, and scope of
14 the benefit provided by parts A and B with respect to indi-
15 viduals who have been determined to have end-stage renal
16 disease and who are entitled to such benefits without regard
17 to section 226A shall in no case be less than the type, dura-
18 tion, and scope of the benefits so provided for individuals
19 entitled to such benefits solely by reason of that section.

20 “(b)(1) *Payments under this title with respect to serv-*
21 *ices, in addition to services for which payment would other-*
22 *wise be made under this title, furnished to individuals who*
23 *have been determined to have end-stage renal disease shall*
24 *include (A) payments on behalf of such individuals to pro-*
25 *viders of services and renal dialysis facilities which meet such*

1 requirements as the Secretary shall by regulation prescribe
2 for institutional dialysis services and supplies (including
3 self-dialysis services in a self-care dialysis unit maintained
4 by the provider or facility), transplantation services, self-
5 care home dialysis support services which are furnished by
6 the provider or facility, and routine professional services
7 performed by a physician during a maintenance dialysis
8 episode if payments for his other professional services
9 furnished to an individual who has end stage renal disease
10 are made on the basis specified in paragraph (3)(A) of this
11 subsection, and (B) payments to or on behalf of such individ-
12 uals for home dialysis supplies and equipment. The require-
13 ments prescribed by the Secretary under subparagraph (A)
14 shall include requirements for a minimum utilization rate
15 for covered procedures and for self-dialysis training
16 programs.

17 “(2)(A) With respect to payments for dialysis serv-
18 ices furnished by providers of services and renal dialysis fa-
19 cilities to individuals determined to have end-stage renal dis-
20 ease for which payments may be made under part B of this
21 title, such payments (unless otherwise provided in this sec-
22 tion) shall be equal to 80 percent of the amounts determined
23 in accordance with subparagraph (B); and with respect to
24 payments for services for which payments may be made
25 under part A of this title, the amounts of such payments

1 *(which amounts shall not exceed, in respect to costs in pro-*
2 *curing organs attributable to payments made to an organ*
3 *procurement agency or histocompatibility laboratory, the*
4 *costs incurred by that agency or laboratory) shall be deter-*
5 *mined in accordance with section 1861(v). Payments shall*
6 *be made to a renal dialysis facility only if it agrees to accept*
7 *such payments as payment in full for covered services, ex-*
8 *cept for payment by the individual of 20 percent of the esti-*
9 *mated amounts for such services calculated on the basis estab-*
10 *lished by the Secretary under subparagraph (B) and the*
11 *deductible amount imposed by section 1833(b).*

12 *“(B) The Secretary shall prescribe in regulations any*
13 *methods and procedures to (i) determine the costs incurred*
14 *by providers of services and renal dialysis facilities in fur-*
15 *nishing covered services to individuals determined to have*
16 *end-stage renal diseases, and (ii) determine, on a cost-related*
17 *basis or other economical and equitable basis (including any*
18 *basis authorized under section 1861(v)), the amounts of*
19 *payments to be made for part B services furnished by such*
20 *providers and facilities to such individuals. Such regulations*
21 *shall provide for the implementation of appropriate incen-*
22 *tives for encouraging more efficient and effective delivery of*
23 *services (consistent with quality care), and shall include,*
24 *to the extent determined feasible by the Secretary, a system*
25 *for classifying comparable providers and facilities, and pro-*

1 *spectively set rates or target rates with arrangements for shar-*
2 *ing such reductions in costs as may be attributable to more*
3 *efficient and effective delivery of services.*

4 “(C) *Such regulations, in the case of services furnished*
5 *by proprietary providers and facilities may include, if the*
6 *Secretary finds it feasible and appropriate, provision for*
7 *recognition of a reasonable rate of return on equity capital,*
8 *providing such rate of return does not exceed the rate of*
9 *return stipulated in section 1861(v)(1)(B).*

10 “(D) *For purposes of section 1878, a renal dialysis*
11 *facility shall be treated as a provider of services.*

12 “(3) *With respect to payments for physicians’ services*
13 *furnished to individuals determined to have end-stage renal*
14 *disease, the Secretary shall pay 80 percent of the amounts*
15 *calculated for such services—*

16 “(A) *on a reasonable charge basis (but may, in*
17 *such case, make payment on the basis of the prevailing*
18 *charges of other physicians for comparable services)*
19 *except that payment may not be made under this sub-*
20 *paragraph for routine services furnished during a main-*
21 *tenance dialysis episode, or*

22 “(B) *on a comprehensive monthly fee or other basis*
23 *for an aggregate of services provided over a period of*
24 *time (as defined in regulations).*

25 “(4) *Pursuant to agreements with approved providers*

1 of services and renal dialysis facilities, the Secretary may
2 make payment to such providers and facilities for the cost of
3 home dialysis supplies and equipment and self-care home
4 dialysis support services furnished to patients whose self-
5 care home dialysis is under the direct supervision of such
6 provider or facility, on the basis of a target reimbursement
7 rate (as defined in paragraph (6)).

8 “(5) An agreement under paragraph (4) shall re-
9 quire that the provider or facility will—

10 “(A) assume full responsibility for directly ob-
11 taining or arranging for the provision of—

12 “(i) such medically necessary dialysis equip-
13 ment as is prescribed by the attending physician;

14 “(ii) dialysis equipment maintenance and re-
15 pair services;

16 “(iii) the purchase and delivery of all neces-
17 sary medical supplies; and

18 “(iv) where necessary (as determined by the
19 Secretary under regulations), the services of trained
20 home dialysis aides;

21 “(B) perform all such administrative functions and
22 maintain such information and records as the Secretary
23 may require to verify the transactions and arrangements
24 described in subparagraph (A);

25 “(C) submit such cost reports, data, and informa-

1 *tion as the Secretary may require with respect to the*
2 *costs incurred for equipment, supplies, and services*
3 *furnished to the facility's home dialysis patient popu-*
4 *lation; and*

5 *“(D) provide for full access for the Secretary to*
6 *all such records, data, and information as he may*
7 *require to perform his functions under this section.*

8 *“(6) The Secretary shall establish, for each calendar*
9 *year, commencing with January 1, 1979, a target reimburse-*
10 *ment rate for home dialysis which shall be adjusted for*
11 *regional variations in the cost of providing home dialysis.*
12 *In establishing such a rate, the Secretary shall include—*

13 *“(A) the Secretary's estimate of the cost of providing*
14 *medically necessary home dialysis supplies and equip-*
15 *ment;*

16 *“(B) an allowance, in an amount determined by the*
17 *Secretary, to cover the cost of providing personnel to aid*
18 *in home dialysis; and*

19 *“(C) an allowance, in an amount determined by the*
20 *Secretary, to cover administrative costs and to provide an*
21 *incentive for the efficient delivery of home dialysis;*

22 *but in no event shall such target rate exceed 70 percent of*
23 *the national average payment, adjusted for regional varia-*
24 *tions, for maintenance dialysis services furnished in ap-*
25 *proved providers and facilities during the preceding fiscal*

1 year. Any such target rate so established shall be utilized,
2 without renegotiation of the rate, throughout the calendar
3 year for which it is established. During the last quarter of
4 each calendar year, the Secretary shall establish a home
5 dialysis target reimbursement rate for the next calendar year
6 based on the most recent data available to the Secretary
7 at the time. In establishing any rate under this paragraph,
8 the Secretary may utilize a competitive bid procedure, a pre-
9 negotiated rate procedure, or any other procedure which the
10 Secretary determines is appropriate and feasible in order to
11 carry out this paragraph in an effective and efficient manner.

12 “(7) For purposes of this title, the term ‘home dialysis
13 supplies and equipment’ means medically necessary supplies
14 and equipment (including supportive equipment) required
15 by an individual suffering from end-stage renal disease in
16 connection with renal dialysis carried out in his home (as
17 defined in regulations), including obtaining, installing, and
18 maintaining such equipment.

19 “(8) For purposes of this title, the term ‘self-care home
20 dialysis support services’, to the extent permitted in regula-
21 tion, means—

22 “(A) periodic monitoring of the patient’s home
23 adaptation, including visits by qualified provider or
24 facility personnel (as defined in regulations), so long as
25 this is done in accordance with a plan prepared and

1 periodically reviewed by a professional team (as defined
2 in regulations) including the individual's physician;

3 “(B) installation and maintenance of dialysis
4 equipment;

5 “(C) testing and appropriate treatment of the
6 water; and

7 “(D) such additional supportive services as the
8 Secretary finds appropriate and desirable.

9 “(9) For purposes of this title, the term ‘self-care di-
10 alysis unit’ means a renal dialysis facility or a distinct part
11 of such facility or of a provider of services, which has been
12 approved by the Secretary to make self-dialysis services, as
13 defined by the Secretary in regulations, available to indi-
14 viduals who have been trained for self-dialysis. A self-care
15 dialysis unit must, at a minimum, furnish the services, equip-
16 ment, and supplies needed for self-care dialysis, have patient-
17 staff ratios which are appropriate to self-dialysis (allowing
18 for such appropriate lesser degree of ongoing medical super-
19 vision and assistance of ancillary personnel than is required
20 for full care maintenance dialysis), and meet such other re-
21 quirements as the Secretary may prescribe with respect to
22 the quality and cost-effectiveness of services.

23 “(c)(1)(A) For the purpose of assuring effective and
24 efficient administration of the benefits provided under this
25 section, the Secretary shall establish, in accordance with

1 such criteria as he finds appropriate, renal disease net-
2 work areas, such network organizations (including a coordi-
3 nating council, an executive committee of such council, and
4 a medical review board, for each network area) as he finds
5 necessary to accomplish such purpose, and a national end
6 stage renal disease medical information system. The Secretary
7 may by regulations provide for such coordination of net-
8 work planning and quality assurance activities and such
9 exchange of data and information among agencies with
10 responsibilities for health planning and quality assurance
11 activities under Federal law as is consistent with the eco-
12 nomical and efficient administration of this section and with
13 the responsibilities established for network organizations un-
14 der this section.

15 “(B) At least one patient representative shall serve as
16 a member of each coordinating council and executive com-
17 mittee.

18 “(C) No person—

19 “(i) with an ownership or control interest (as de-
20 fined in section 1124(a)(3)) in a facility or provider
21 which provides services referred to in section 1861(s)
22 (2)(F) or provides kidney transplants, or

23 “(ii) who has received remuneration from any such
24 facility or provider in excess of such amounts as con-

1 *stitute reasonable compensation for services or goods sup-*
 2 *plied to such facility or provider, or*

3 *“(iii) who is the spouse, parent, son, daughter,*
 4 *brother, or sister of a person described in clause (i) or*
 5 *(ii) (or who bears such relationship to the spouse of*
 6 *such a person),*

7 *shall serve as a member of any network organization.*

8 *“(2) The network organizations of each network shall*
 9 *be responsible, in addition to such other duties and functions*
 10 *as may be prescribed by the Secretary, for—*

11 *“(A) encouraging, consistent with sound medical*
 12 *practice, the use of those treatment settings most compati-*
 13 *ble with the successful rehabilitation of the patient;*

14 *“(B) developing criteria and standards relating to*
 15 *the quality and appropriateness of patient care; and*

16 *“(C) evaluating the procedures by which facilities*
 17 *and providers in the network assess the appropriateness*
 18 *of patients for proposed treatment modalities.*

19 *“(d) Notwithstanding any provision to the contrary*
 20 *in section 226, any individual who donates a kidney for*
 21 *transplant surgery shall be entitled to benefits under parts*
 22 *A and B of this title with respect to such donation. Reim-*
 23 *bursement for the reasonable expenses incurred by such an*
 24 *individual with respect to a kidney donation shall be made*

1 *(without regard to the deductible, premium, and coinsur-*
2 *ance provisions of this title), in such manner as may be*
3 *prescribed by the Secretary in regulations, for all reasonable*
4 *preparatory, operation, and postoperation recovery expenses*
5 *associated with such donation, including but not limited to*
6 *the expenses for which payment could be made if he were an*
7 *eligible individual for purposes of parts A and B of this*
8 *title without regard to this subsection. Payments for post-*
9 *operation recovery expenses shall be limited to the actual*
10 *period of recovery.*

11 “(e)(1) *Notwithstanding any other provision of this*
12 *title, the Secretary may, pursuant to agreements with*
13 *approved providers of services and renal dialysis facilities,*
14 *reimburse such providers and facilities (without regard to*
15 *the deductible and coinsurance provisions of this title) for*
16 *the reasonable cost of the purchase, installation, maintenance*
17 *and reconditioning for subsequent use of artificial kidney*
18 *and automated dialysis peritoneal machines (including sup-*
19 *portive equipment) which are to be used exclusively by*
20 *entitled individuals dialyzing at home.*

21 “(2) *An agreement under this subsection shall require*
22 *that the provider or facility will—*

23 “(A) *make the equipment available for use only*
24 *by entitled individuals dialyzing at home;*

25 “(B) *recondition the equipment, as needed, for*

1 *reuse by such individuals throughout the useful life of*
2 *the equipment, including modification of the equipment*
3 *consistent with advances in research and technology;*

4 *“(C) provide for full access for the Secretary to*
5 *all records and information relating to the purchase,*
6 *maintenance, and use of the equipment; and*

7 *“(D) submit such reports, data, and information*
8 *as the Secretary may require with respect to the cost,*
9 *management, and use of the equipment.*

10 *“(3) For purposes of this section, the term ‘sup-*
11 *portive equipment’ includes blood pumps, heparin pumps,*
12 *bubble detectors, other alarm systems, and such other items*
13 *as the Secretary may determine are medically necessary.*

14 *“(f)(1) The Secretary shall initiate and carry out, at*
15 *selected locations in the United States, pilot projects under*
16 *which financial assistance in the purchase of new or used*
17 *durable medical equipment for renal dialysis is provided to*
18 *individuals suffering from end stage renal disease at the*
19 *time home dialysis is begun, with provision for a trial*
20 *period to assure successful adaptation to home dialysis*
21 *before the actual purchase of such equipment.*

22 *“(2) The Secretary shall conduct experiments to*
23 *evaluate methods for reducing the costs of the end stage*
24 *renal disease program. Such experiments shall include*
25 *(without being limited to) reimbursement for nurses and*

1 *dialysis technicians to assist with home dialysis, and reim-*
2 *bursement to family members assisting with home dialysis.*

3 “(3) *The Secretary shall conduct experiments to evalu-*
4 *ate methods of dietary control for reducing the costs of the*
5 *end stage renal disease program, including (without being*
6 *limited to) the use of protein-controlled products to delay*
7 *the necessity for, or reduce the frequency of, dialysis in the*
8 *treatment of end stage renal disease.*

9 “(4) *The Secretary shall conduct a comprehensive*
10 *study of methods for increasing public participation in kidney*
11 *donation and other organ donation programs.*

12 “(5) *The Secretary shall conduct a full and complete*
13 *study of the reimbursement of physicians for services fur-*
14 *nished to patients with end stage renal disease under this*
15 *title, giving particular attention to the range of payments to*
16 *physicians for such services, the average amounts of such*
17 *payments, and the number of hours devoted to furnishing*
18 *such services to patients at home, in renal disease facilities,*
19 *in hospitals, and elsewhere.*

20 “(6) *The Secretary shall conduct a study of the num-*
21 *ber of patients with end stage renal disease who are not*
22 *eligible for benefits with respect to such disease under this*
23 *title (by reason of this section or otherwise), and of the*
24 *economic impact of such noneligibility of such individuals.*
25 *Such study shall include consideration of mechanisms where-*

1 by governmental and other health plans might be instituted
2 or modified to permit the purchase of actuarially sound
3 coverage for the costs of end stage renal disease.

4 “(7) The Secretary shall conduct a study of the medi-
5 cal appropriateness and safety of cleaning and reusing
6 dialysis filters by home dialysis patients. In such cases in
7 which the Secretary determines that such home cleaning and
8 reuse of filters is a medically sound procedure, the Secretary
9 shall conduct experiments to evaluate such home cleaning
10 and reuse as a method of reducing the costs of the end stage
11 renal disease program.

12 “(8) The Secretary shall submit to the Congress no
13 later than October 1, 1979, a full report on the experiments
14 conducted under paragraphs (1), (2), (3), and (7) and
15 the studies under paragraphs (4), (5), (6), and (7). Such
16 report shall include any recommendations for legislative
17 changes which the Secretary finds necessary or desirable as
18 a result of such experiments and studies.

19 “(9) The Secretary shall submit to the Congress on
20 October 1, 1978, and on October 1 of each year thereafter,
21 a report on the end stage renal disease program, including
22 but not limited to—

23 “(1) the number of patients, nationally and by
24 renal disease network, on dialysis (self-dialysis or other-
25 wise) at home and in facilities;

1 “(2) the number of new patients entering dialysis
2 at home and in facilities during the year;

3 “(3) the number of facilities providing dialysis and
4 the utilization rates of those facilities;

5 “(4) the number of kidney transplants, by source
6 of donor organ;

7 “(5) the number of patients awaiting organs for
8 transplant;

9 “(6) the number of transplant failures;

10 “(7) the range of costs of kidney acquisitions, by
11 type of facility and by region;

12 “(8) the number of facilities providing transplants
13 and the number of transplants performed per facility;

14 “(9) patient mortality and morbidity rates;

15 “(10) the average annual cost of hospitalization for
16 ancillary problems in dialysis and transplant patients,
17 and drug costs for transplant patients;

18 “(11) medicare payment rates for dialysis, trans-
19 plant procedures, and physician services, along with any
20 changes in such rates during the year and the reasons
21 for those changes;

22 “(12) the results of cost-saving experiments;

23 “(13) the results of basic kidney disease research
24 conducted by the Federal Government, private institu-
25 tions, and foreign governments;

1 “(14) information on the activities of medical re-
2 view boards and other network organizations; and

3 “(15) estimated program costs over the next five
4 years.”.

5 SEC. 3. (a) Section 226(a) of the Social Security Act
6 is amended—

7 (1) by striking out “specified in subparagraph
8 (B)” and inserting in lieu thereof “specified in para-
9 graph (1)” ; and

10 (2) by striking out “specified in subparagraphs
11 (A) and (B)” and inserting in lieu thereof “specified
12 in paragraphs (1) and (2)”.

13 (b) Paragraphs (2) and (3) of section 226(e) of
14 such Act (as redesignated by subsection (b)(2) of the first
15 section of this Act) are each amended by striking out “sub-
16 section b” and inserting in lieu thereof “subsection (b)”.

17 SEC. 4. (a) Section 1811 of such Act is amended—

18 (1) by striking out “section 226” and inserting in
19 lieu thereof “sections 226 and 226A” ;

20 (2) by striking out “and” at the end of clause (1),
21 and inserting in lieu thereof a comma ; and

22 (3) by inserting immediately before the period the
23 following: “, and (3) certain individuals who do not
24 meet the conditions specified in either clause (1) or (2)

1 *but who are medically determined to have end stage*
2 *renal disease”.*

3 *(b) Section 1833(a)(1) of the Social Security Act is*
4 *amended—*

5 *(1) by striking out “and” at the end of clause (C),*
6 *and*

7 *(2) by adding the following after “and” in clause*
8 *(D):*

9 *“(E) with respect to services furnished to individ-*
10 *uals who have been determined to have end stage renal*
11 *disease, the amounts paid shall be determined subject to*
12 *the provisions of section 1881, and”.*

13 *(c) Section 1833(a)(2) of such Act is amended by*
14 *inserting “(unless otherwise specified in section 1881)”*
15 *after “other services”.*

16 *(d) Section 1861(s)(2) of such Act is amended—*

17 *(1) by striking out “and” at the end of clause (D),*

18 *(2) by inserting “and” at the end of clause (E),*

19 *and*

20 *(3) by adding the following new clause after sub-*
21 *clause (E):*

22 *“(F) home dialysis supplies and equipment, self-*
23 *care home dialysis support services, and institutional*
24 *dialysis services and supplies;”.*

1 (e) The first sentence of section 1866(a)(2)(A) of
 2 such Act is amended by inserting the following before the
 3 period: “(but in the case of items and services furnished
 4 to individuals with end stage renal disease, an amount equal
 5 to 20 percent of the estimated amounts for such items and
 6 services calculated on the basis established by the Secretary)”.

7 (f) Section 1814(b)(1) of such Act is amended by
 8 inserting “and as further limited by section 1881(b)(2)
 9 (B)” after “1861 (v)”.

10 SEC. 5. The third sentence of section 1817(b) of the
 11 Social Security Act, the third sentence of section 1841(b) of
 12 such Act, and section 1876(b)(2)(B) of such Act, are each
 13 amended by striking out “Commissioner of Social Security”
 14 and inserting in lieu thereof “Administrator of the Health
 15 Care Financing Administration”.

16 SEC. 6. The amendments made by the preceding sections
 17 of this Act shall become effective with respect to services, sup-
 18 plies, and equipment furnished after the third calendar month
 19 which begins after the date of the enactment of this Act, except
 20 that those amendments providing for the implementation of an
 21 incentive reimbursement system for dialysis services furnished
 22 in facilities and providers shall become effective with respect
 23 to a facility’s or provider’s first accounting period which
 24 begins after the last day of the twelfth month following the

1 month of the enactment of this Act, and those amendments
 2 providing for reimbursement rates for home dialysis shall
 3 become effective on July 1, 1979.

4 REIMBURSEMENT FOR SERVICES OF PHYSICIANS PROVIDED
 5 IN TEACHING HOSPITALS

6 SEC. 7. Section 15(d) of Public Law 93-233 (as
 7 amended by section 7(c) of Public Law 93-368 and the first
 8 section of Public Law 94-368) is amended by striking out
 9 "October 1, 1977" and inserting in lieu thereof "October 1,
 10 1978".

11 TECHNICAL AMENDMENTS TO MEDICARE-MEDICAID ANTI-
 12 FRAUD AND ABUSE AMENDMENTS

13 SEC. 8. (a) The first sentence of section 1905(c) of
 14 the Social Security Act is amended—

15 (1) by striking "and (3)" and inserting in lieu
 16 thereof "(3)"; and

17 (2) by striking out the period at the end thereof
 18 and inserting in lieu thereof the following "and (4)
 19 meets the requirements of section 1861(j)(14) with
 20 respect to protection of patients' personal funds."

21 (b) The fourth sentence of section 1905(c) of such Act
 22 is amended by striking out "clauses (2) and (3)" and in-
 23 serting in lieu thereof "clauses (2), (3), and (4)".

24 (c) The Secretary of Health, Education, and Welfare
 25 shall, by regulation, define those costs which may be charged

1 to the personal funds of patients in intermediate care facil-
 2 ities who are individuals receiving medical assistance under
 3 a State plan approved under the provisions of title XIX of
 4 the Social Security Act, and those costs which are to be
 5 included in the reasonable cost or reasonable charge for in-
 6 termediate care facility services as determined under the
 7 provisions of such title.

8 (d)(1) The amendments made by subsections (a) and
 9 (b) shall become effective on July 1, 1978.

10 (2) The Secretary of Health, Education, and Welfare
 11 shall issue the regulations required under subsection (c)
 12 within 90 days after the date of enactment of this Act but
 13 not later than July 1, 1978.

14 (e) Section 20(c)(2) of the Medicare-Medicaid Anti-
 15 Fraud and Abuse Amendments (Public Law 95-142) is
 16 amended by striking out "section 1905(g)" and inserting in
 17 lieu thereof "section 1903(g)".

Passed the House of Representatives September 12,
 1977.

Attest:

EDMUND L. HENSHAW, JR.,

Clerk.

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Calendar No. 656

95TH CONGRESS
2D SESSION

H. R. 8423

[Report No. 95-714]

AN ACT

To amend titles II and XVIII of the Social Security Act to make improvements in the end stage renal disease program presently authorized under section 226 of that Act, and for other purposes.

SEPTEMBER 13, 1977

Read twice and referred to the Committee on Finance

MARCH 22 (legislative day, FEBRUARY 6), 1978

Reported with an amendment